REPUBLIC OF TÜRKİYE

MINISTRY OF TRADE

DIRECTORATE GENERAL FOR PRODUCT SAFETY AND INSPECTION

GUIDE ON IMPORT INSPECTION OF MEDICAL DEVICES

Handbook on Implementation Principles

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1. SCOPE AND LEGAL BASIS

This Guide sets out the procedures and principles for conducting and finalizing physical inspections of products covered by the Medical Device Import Inspection Communiqué, prepared and implemented by the Ministry of Trade pursuant to Article 455 of Presidential Decree No. 1 on the Presidential Organization; the Product Safety and Technical Regulations Law No. 7223 dated 5 March 2020; the Decision on the Technical Regulations Regime enacted by Presidential Decision No. 6038 dated 14 September 2022; and the Regulation on Technical Regulations in Foreign Trade published in the Official Gazette No. 32281 dated 16 August 2023.

Unless otherwise stated, instructions issued following company applications on matters not covered by inspection guides are not individual in nature and also apply to other companies in the same situation.

The principles and provisions in this Guide may not be understood or interpreted outside the scope of legislation concerning Product Safety and Technical Regulations.

2. IMPORT INSPECTION APPLICATIONS

2.1 Application by the Importing Company

For products included in the "List of Products Subject to Inspection" in Annex 1 to the Communiqué, import inspection applications are made before registration of the customs declaration, within the framework of Article 181(4) of the Customs Regulation.

The provisions of Article 5 of the Communiqué apply to applications. Accordingly, the user authorized to act on behalf of the company submits the application through TAREKS by entering data concerning the import consignment via "Login to E-Signature Applications" in the "E-Signature Applications" section of the Ministry website. Upon application, TAREKS assigns the company an application number solely to enable it to track its transactions before the relevant inspection unit.

2.2 Exemptions and Exceptions

The characteristics of applications granted exemption or exception from import inspection are regulated in Article 6 of the Communiqué. Accordingly, products accompanied by an A.TR movement certificate, returned goods, and products specified in Part Five of the Decision on the Implementation of Certain Articles of Customs Law No. 4458, annexed to Council of Ministers Decision No. 2009/15481 dated 9 September 2009, are exempt from physical inspection.

However, pursuant to the last paragraph of Article 6 of the Communiqué, applications accompanied by an A.TR certificate may also be referred to physical inspection where necessary. In these assessments, in addition to risk analysis, such matters as the results of examination of documents submitted in the company's previous applications, whether it submitted a document not issued by its purported issuer, and whether it made cancellation or duplicate applications are taken into account.

2.3 Submission of Application Documents

For every application, the documents specified in the first and second paragraphs of Annex 2 to the Communiqué must be uploaded to the system. For products referred to physical inspection, the documents specified in the third, fourth and fifth paragraphs of Annex 2 must be uploaded completely to the Risk-Based Control System in Foreign Trade (TAREKS) electronically within twenty business days, including the application date. If documents are missing and the company wishes to continue the application, the system may grant additional time. If the required documents are not uploaded within that period, the application is finalized by the system as "Rejection: Missing Document." An application finalized by the system as "Rejection: Missing Document" due to missing Annex 2 documents may be reopened for inspection once through the additional-time request button in the system.

If documents required for a physically inspected application cannot be uploaded to TAREKS owing to a technical problem, they are submitted in person to the relevant Group Presidency. When submitted in person, application documents may be delivered by persons authorized under a power of attorney. In that case, a power of attorney demonstrating authority to act for the importer must be submitted. No inspection is conducted if no power of attorney is submitted.

Where application files submitted through TAREKS for products covered by the same customs document contain multiple customs tariff codes, or products of different type, origin, brand or model under the same code, or products from different manufacturers, it is sufficient to upload common and applicable documents—such as the customs document, invoice and declarations of conformity—once to TAREKS for each application file.

3. INSPECTION PROCESSES

The inspection process begins when an application made through TAREKS by the user authorized to act on behalf of the company is referred to physical inspection. The import inspection process referred to as physical inspection is carried out so as to include one or more of the following, in sequence:

- Verification of TAREKS application information
- Scope check
- Document review
- Physical inspection

First, TAREKS application information is checked and the scope check is performed. Once it is understood that the products fall within the scope of the relevant legislation, information and documents concerning the product are reviewed under that legislation. If the inspection units form a suspicion that products are risky, the inspection may be assessed at a higher inspection stage.

3.1 Verification of Application Information

The relevant inspection unit checks consistency between the information declared in the TAREKS application and documents submitted through TAREKS. If application information is declared incorrectly, the inspection unit must cancel the application and the importer must apply again in the system. However, where brand and model have inadvertently been declared incorrectly, necessary corrections may be made in the system without cancelling the application after consultation with the relevant inspection unit. If products listed in the Annex to the Communiqué and imported under the cold chain—especially in vitro diagnostic products—are identified, they must be given priority in the physical-inspection schedule and inspection processes must be completed promptly.

3.2 Scope Check

For applications referred to physical inspection by TAREKS, it is checked whether the product falls within the scope of the relevant technical legislation and whether, in terms of the description corresponding to its customs tariff code, it is among the products intended for inspection by the Ministry. Applications concerning products found to be out of scope are finalized as "Out of Scope: Inspection Result."

On the first importation of products declared out of scope by the company representative through TAREKS, the product is referred to physical inspection; imports of products found to be out of scope are finalized as "Out of Scope: Inspection Result." For subsequent imports of products previously found out of scope, whether products are referred to physical inspection is determined by risk analysis.

3.3 Review of Application Documents

Information and documents submitted by the company are checked in order to determine whether products subject to the application comply with their technical legislation.

Documents must principally be submitted in Turkish. Documents submitted in English are also accepted. Where necessary, notarized translations of documents may be requested.

The EU Declaration of Conformity uploaded by the company must contain the elements specified in Annex 2. Where a product is subject to more than one technical regulation requiring an EU Declaration of Conformity, the manufacturer demonstrates, by issuing a single EU Declaration of Conformity, that it has fulfilled all applicable requirements of those technical regulations.

Test reports submitted within the inspection must be current, issued by accredited laboratories, and dated before the transport document. The party commissioning the test must be the manufacturer or importer of the product. Test reports must contain product-identifying information such as brand and model/serial number. To establish a causal link between the product and the test report, information on the products or their packaging must match the

information in the test report. Where no such link can be established, products must be sampled and tested, subject to the company's acceptance.

Photographs uploaded to the system under a TAREKS application must belong to the imported product and have been taken within the customs area. If, during physical inspection, the uploaded photographs are found not to be of the same product, the matter is reported to the Directorate General. If photographs were uploaded in order to abuse inspection procedures, the matter is considered in TAREKS risk assessment.

Where review of the information and documents submitted with the application and of the product reveals a need for more detailed investigation, or where documents and information submitted by the importer do not belong to the product, and it is concluded that the company did not intend to mislead inspection units, the company is requested to complete the product documents within an additional 45 days. If requested documents are not submitted within the 45-day additional period, starting from the date the inspector first requested a document through TAREKS, the application is finalized as "Rejection: Missing Document." In the event of missing documents, applications must not be finalized by the inspector through cancellation.

3.4 Physical Inspection

Where the system refers products to physical inspection, products may be physically inspected to establish a causal link between the products and uploaded documents and to eliminate doubts that may arise for products referred to document review. During physical inspection, it is essential to examine the product's structure and characteristics, determine whether all required reports have been submitted, and identify tests to be requested for products for which reports cannot be submitted. Details of identified matters must be recorded in the Physical Inspection/Sampling Report in Annex 1.

During inspection and sampling in the customs area for applications referred to physical inspection, persons accompanying the inspection must submit a power of attorney demonstrating their authority to act for the importer. No inspection is conducted if no power of attorney is submitted.

All communications with the inspection unit concerning products to be physically inspected must proceed through the "Inspection Messages" tab. If company representatives are absent at the scheduled physical-inspection time or products are not ready, the inspection schedule is redrawn without regard to the application date. If products are not in the inspection area, the application is finalized as "Rejection: Inspection Result."

During physical inspection, photographs of the product should be taken where possible and archived for use when necessary. Moreover, even where medical-device products are referred to document review through the system, physical inspection is not performed if product visuals, required documents or label information are unavailable or insufficient.

An important point during inspection is that there should not be significant differences or contradictions between the class declared by the importer and classes stated in the table. In such suspicious cases, the matter must be reported to the Directorate General for transmission to the Ministry of Health on a case-by-case basis (product, company, intended purpose, possible class, declared class, etc.).

3.4.1 Marking Check

CE Marking: The CE marking must conform to the form specified in the CE Marking Regulation published in Official Gazette No. 31493 dated 27 May 2021. Except for reduction or enlargement while observing the proportions in the drawing, the design may not be altered. Unless otherwise provided in the relevant technical regulation, it must be at least 5 mm in size and affixed visibly, legibly and indelibly to the product or its data plate; where this is impossible due to the nature of the product or its permanence cannot be guaranteed, it must be affixed to the packaging and accompanying documents required by the relevant technical regulation. Where companies declare that affixing the CE marking is impossible due to the product's nature, inspections proceed by considering markings on equivalent products.

CE marking on a durable paper label is also accepted as appropriately affixed, provided it is visible, legible and indelible; is printed on the same label together with other product information (product image, features, instructions for use, manufacturer/importer address information, other markings, warnings, etc.); and gives a definite impression that it was affixed during manufacture. Labels made of materials such as A4 paper and not permanent on the product are excluded. The presence of the CE marking together with other product information on that label is deemed sufficient to indicate that it was affixed during manufacture.

If the CE marking is not affixed in the dimensions required by the Regulation, inspection is finalized as "Conditional Acceptance: Warning," provided no other non-compliance is found after considering criteria such as product design, nature, dimensions and label layout, and test reports are compliant. Examples of compliant and non-compliant CE markings are shown in Annex 5.

For sterile-packaged products, the CE marking must appear on the sterile package and/or product as well as the sales packaging. However, for products that lose sterility when the sterile packaging is opened, CE marking on the sterile package and sales packaging is sufficient without looking at the product. For products in multiple sterile packages, if opening the package makes it impossible to place the products on the market again, CE marking on the package is sufficient and is not sought on each individual product. For sterile-packaged products, CE marking is not sought on the product itself; it is sufficient on the sterile and sales packaging. For non-sterile products, CE marking must be on both the product and sales packaging. The unit sterile package must not be opened in order to preserve product sterility.

Notified Body Identification Number: As a rule, a difference between the notified body identification number on the product and that on the product documents constitutes non-

compliance. Exceptionally, where, under the relevant European Union Regulations governing transitional provisions for certain medical devices and in vitro diagnostic medical devices, it is demonstrated that a different notified body designated under the MDR may make changes, including to the CE marking, on the labels of legacy devices, and there is a transitional arrangement between notified bodies, the situation may be assessed as an exception. When the relevant legislation and the European Commission's questions-and-answers document are assessed together, there is considered to be no obstacle to the MDR-designated notified body placing its own identification number on device labelling, provided the tripartite agreement explicitly states that it has taken over surveillance responsibility.

For detailed information on UDI, see Section 5.2; for a UDI example, see Annex 4.

3.4.2 Inspection of Adapters Supplied with Products

Even if the main product is outside the scope of the relevant technical legislation, test reports may be requested and/or removable (non-integral) adapters supplied with the product may be tested where necessary. Therefore, if an external adapter is included with the product/unit package, its marking information is also checked. If adapters are found non-compliant, they may be handled and separated from the main products, provided it is documented that they have been surrendered to the customs authority where they are located for return to origin, transit directly or via a free zone to a third country, sale for export, or disposal by destruction at the owner's expense. Following handling, the main product must be tested with compliant adapters; if the test is positive, the application is finalized after handling all products in the application.

If adapters supplied with products referred to testing by TAREKS are also tested and the results are positive, inspection is deemed positive in this respect without seeking an EU Declaration of Conformity and/or marking information for the adapters, including CE marking, brand and model. If adapter test results are negative but main-product results are positive, if the importer does not accept separate testing of the adapters, or if the main products are also found non-compliant due to the adapters, the handling provisions in Section 4.4.2 apply.

3.4.3 Warnings

During physical inspection, it must be checked whether warnings required on the product or packaging by the applicable legislation are present in the manner prescribed. If warnings required by the relevant technical legislation are incomplete or absent, their handling in the customs area may be permitted. For explanations of medical-device symbols used for active and non-active devices, see Annex 6.

3.5 Testing Procedures

Products are sent for testing—subject to the company's acceptance—when companies cannot submit a test report, inspectors develop serious suspicion concerning products, or TAREKS directly refers products to testing.

For applications referred to testing, inspectors sample products and send them for testing, provided cargo and testing costs are borne by the importer. Samples are sent by the relevant inspection unit to one of the designated laboratories in rotation. Inspections are finalized according to the test result. The result of a sample applies to all line items represented by it. The number of samples must be kept to a minimum; sample quantities are determined according to the product's technical legislation, although additional samples may be taken where necessary.

During sampling, required information is entered in the Physical Inspection/Sampling Report in Annex 1, which is signed by both the inspector and the company's authorized representative. At this stage, the representative's power of attorney is checked and the inspection unit photographs the samples. The sample retained by the inspection unit is entered in the sample register.

Witness samples are retained by the Group Presidency. The objection period for test results is 15 business days. If a test result is challenged, witness samples are retested, where possible, by a testing body different from the first laboratory to which the products were sent.

For files referred to testing by the system but which cannot be tested due to testing capabilities, product characteristics or product quantity, the process must continue as test-report review. Such cases must promptly be reported to the Directorate General, together with the relevant customs tariff code and the reason testing was not possible.

If the importing company does not accept that products be sent for testing, the application is finalized as "Rejection: Inspection Result" on the basis of its written declaration.

3.6 Application Cancellation Procedures

Cancellation is a procedure solely enabling an application to be repeated after correcting material error(s) identified during review of the existing application. Cancellation of applications under inspection may be performed only by the inspector.

Where one or more application details other than brand and model have been entered incorrectly or incompletely, the relevant inspection unit sends an explanatory message through the "Inspection Messages" tab and inspection continues to the final stage. If it is understood at the end of inspection that products cannot pass import inspection, the application is finalized as "Rejection"; otherwise, to enable the company to correct its error, it is finalized as "Cancellation: Inspector Cancellation." The material error must be stated in an inspector note when closing the application. Where brand and model have inadvertently been declared incorrectly, the company may make necessary corrections through the system without cancellation after consultation with the relevant inspection unit.

Where applications for products inspected by the inspection unit are cancelled due to material errors after completion of inspection, inspection procedures for the same consignment are conducted according to the inspection type assigned by TAREKS. If transfer of the inspected products to another company is requested while inspection continues, inspection is carried out

under the existing application. If products are compliant, after documents evidencing transfer are submitted, the transferor company's application is finalized as "Cancellation: Inspector Cancellation." Any suspicion concerning a transfer is reported to the Directorate General.

Cancellation requests made by companies other than in the cases above are not accepted. A request to cancel an application because products are returned to origin or transited to another country is not accepted. However, the application may be finalized as rejected upon a written petition from the company requesting rejection.

3.7 Duplicate Applications

A new TAREKS application/opening of a line item to import products from an application finalized as rejected, or to avoid inspection for products subject to an ongoing application/application line item, is called a duplicate application. This prevents risk analysis from operating effectively and correctly.

To prevent duplicate applications, where material error is identified in application information, the following must be observed:

- Once it is understood that the application must be cancelled, company officials must be notified immediately by the relevant inspection unit, and cancellation must be performed after the inspection process.
- The inspection message and any discussion with company officials must clearly remind them that no new application may be made for products subject to cancellation before cancellation is confirmed in the system; otherwise, sanctions may be imposed on the company and user.

If a duplicate application by a company is identified, inspections are finalized directly as "Rejection: Misleading Transaction" and the matter is reported to the Directorate General.

3.8 Document Not Issued by Its Purported Issuer

If there is doubt about the authenticity of a document submitted under import inspection, its authenticity is investigated through the issuer's website. If this is not possible, the issuer is contacted by email and authenticity is confirmed. If the response states that documents are counterfeit or are not correct, valid or consistent, the document is treated as not issued by its purported issuer. If information requested from the relevant body by email is not sent within 20 days, the matter is reported to the Directorate General.

Where a document submitted to TAREKS is found not to have been issued by its purported issuer, replacement of the document is not requested. The inspection is finalized directly as "Rejection: Document Not Issued by Its Purported Issuer" and the matter is reported to the Directorate General. Administrative sanctions under Article 13 of the Communiqué are applied to both the company and user.

In addition, where the original document appears on the relevant body's website, this must be stated in the letter to the Directorate General; if the body is contacted by email, the complete original document or its cover page must be attached to that letter where obtained; and if the correct document or cover page cannot be obtained, this must be stated in the letter addressed to the Directorate General.

If alteration or a transaction casting doubt on accuracy is identified in information and documents submitted for one application line item, the provisions above apply only to the line item(s) in doubt; inspection of the other line item(s) is completed according to the relevant technical legislation.

3.9 Attempts to Mislead the System

Attempts intended to prevent risk analysis from functioning correctly are considered misleading transactions. Upon detection of such attempts, the relevant application is finalized as "Rejection: Misleading Transaction."

4. FINALIZATION OF THE INSPECTION

4.1 Applications to Be Finalized with Conditional Acceptance

4.1.1 Conditional Acceptance: Minor Deficiency

Unless otherwise specified in technical legislation, if importer information required on the product/packaging cannot be identified, the application is finalized as "Conditional Acceptance–Minor Deficiency: Inspection Result," so that it may be determined through market surveillance and inspection whether the deficiency has been remedied.

4.1.2 Conditional Acceptance: Further Processing

Under Article 5(2)(f) of the Framework Regulation on Market Surveillance and Inspection of Products, published in Official Gazette No. 31537 dated 10 July 2021, unless otherwise specified in relevant technical legislation, products obtained by a manufacturer from another manufacturer, or imported by the manufacturer/supplier where the manufacturer is abroad, in order to perform further processing such as assembly, packaging, processing or labelling, are not considered placed on the market. Where they are not considered placed on the market, applications may be assessed within the further-processing practice.

For an application to be assessed as further processing, the importing company must be a manufacturer/supplier. To approve such requests, companies must be asked for a capacity report, industrial registry certificate and, where available, explanatory documents concerning production and final products to prove that they are manufacturers; those documents must be examined to verify manufacturer status. The importer is requested to submit the capacity report and the undertaking in the specimen in Annex 7, explaining the operations to be performed on the product and stating that final products compliant with applicable technical legislation will be placed on the market.

To finalize an inspection as further processing, it must be verified from the capacity report that the manufacturer produces the relevant final product.

In particular, requests for further processing must be made for medical devices imported in bulk to be sterilized at domestic facilities. The company carrying out sterilization may do so only for products for which it will present itself as the manufacturer; other importers do not have such a right.

In these cases, the company carrying out sterilization must hold certificates issued by a Notified Body documenting that its production facilities comply with the relevant regulation for sterilization. A company importing in this manner for the first time must be required to submit that certificate subsequently; for subsequent imports of the same product by companies that have previously performed this operation, submission of the certificates is mandatory. When the certificate is submitted, those products are assessed under further processing and inspections are finalized as "Conditional Acceptance: Further Processing."

4.1.3 Conditional Acceptance: Warning

Where conformity markings required by the product's technical legislation (such as CE marking) are not affixed in the dimensions specified in the relevant legislation, inspection is finalized once only as "Conditional Acceptance: Warning," provided no other non-compliance is found after considering product design, nature, dimensions and label layout, and test reports are compliant. If the matter subject to warning recurs in subsequent applications, the application is finalized as "Rejection: Missing Marking."

4.1.4 Conditional Acceptance: Component/Part

If research establishes that products to be imported under the Medical Device Regulations are used as intermediate materials, and information and documents are submitted to evidence a causal link between the intermediate product and the main product in which it will be used—such as a letter from the relevant Notified Body stating that products are used as intermediate material in another medical device and need not bear CE marking, or catalogues and similar documents confirming use in the main product—documents relating to the main product (such as the EU Declaration of Conformity) are completed and applications are finalized as "Conditional Acceptance–Component/Part: Inspection Result."

4.2 Applications to Be Finalized with Rejection

If non-compliance with the relevant legislation is identified as a result of inspection, the application is finalized as "Rejection: Inspection Result." The reason for non-compliance must be written in detail as an inspector note and transmitted to the user using the message in Annex 8. The customs authority is notified in writing stating the reason for rejection, and customs authorities do not permit importation of the product.

Where products need to be tested and the importer does not accept testing and requests non-compliance by petition, the application is finalized as "Rejection: Inspection Result."

If companies enter information for more than one product (brand, model, quantity, etc.) collectively in a single TAREKS line item, and it is understood that the line includes products to be rejected and products whose import may be permitted, a new TAREKS application is made for compliant products; after that application is made, the existing application is finalized as "Rejection: Inspection Result." A new TAREKS application may be made only for compliant products. If a new application is made for non-compliant products, duplicate-application rules apply for those products.

If it is found that applications referred to physical inspection through TAREKS and still under inspection are being avoided through unlawful means, such as use of an invalid TPS number or unauthorized transit trade, the absence of products from customs and those avoidance acts are taken into account; the application is finalized as "Rejection: Misleading Transaction" and the matter is reported to the Directorate General.

If products are found not to be in the customs area during inspection for reasons such as incomplete delivery of the order or products not yet having arrived in the customs area, and therefore no finding or review can be made, the relevant application line is finalized as "Rejection: Inspection Result."

In medical-device inspections, if companies cannot submit an EU Declaration of Conformity containing Basic UDI-DI information, the application is finalized as "Rejection: Inspection Result." If UDI is absent from the product and packaging even though applicable, the application is finalized as "Rejection: Missing Marking."

4.3 Conformity Inspection Outcomes

Outcome	Explanation
Acceptance: Inspection Result	If physical inspection identifies no non-compliance with applicable technical legislation, the application is finalized as "Acceptance: Inspection Result."
Out of Scope: Inspection Result	If products are outside the relevant technical legislation or outside products intended for Ministry inspection in terms of the customs-tariff-code description, the application is finalized as "Out of Scope: Inspection Result."
Conditional Acceptance–Minor Deficiency: Inspection Result	Applications are finalized this way to ensure deficiencies identified during inspection are remedied immediately after completion of

	import formalities and in all cases before placing products on the market.
Conditional Acceptance–Further Processing: Inspection Result	Applications for semi-finished products intended for further processing, for which required documents have been obtained to turn them into final products after placement on the market, are finalized this way.
Conditional Acceptance–Warning: Inspection Result	If conformity markings required on the product are not affixed in the appropriate size, and there is no other non-compliance, the application is finalized this way.
Conditional Acceptance–Component/Part: Inspection Result	If products are found to be used as intermediate materials, applications are finalized this way provided information and documents (Notified Body letter, catalogue, etc.) evidence the causal link with the main product. See Section 4.1.4.
Rejection: Inspection Result	If inspection identifies non-compliance with applicable legislation, the application is finalized this way.
Rejection: Missing Document	If requested documents are not submitted within the period granted during inspection, the inspection is finalized this way.
Rejection: Missing Marking	If conformity markings required under applicable legislation are absent from the product, the application is finalized this way.
Rejection: Document Not Issued by Its Purported Issuer	Applications in which a document not issued by its purported issuer is found to have been uploaded are finalized this way.
Rejection: Misleading Transaction	If a duplicate transaction is detected or attempts are made to prevent risk analysis from functioning properly, the application is finalized this way.

Cancellation: Inspector Cancellation	Applications with no non-compliance but containing information inadvertently declared by the company that needs correction are finalized this way.

4.4 Handling Requests

Handling requests may be considered except for correction operations requiring technical intervention, such as impacts, notches, etc. For products non-compliant with technical legislation in respects that can be remedied in the customs area—such as Turkish instructions for use, labelling, marking (except brand, model and CE marking), or packaging—correction requests that pose no inconvenience in terms of health, safety, environmental protection or correct consumer information are notified in writing to the relevant inspection unit.

If the request is approved, the company is granted up to 30 days for handling. Handling must be performed in an area under the supervision of the customs directorate. Once handling is completed within or at the end of the 30-day period, the company must submit a written petition to the inspection unit stating that deficiencies have been completed. After submission, the products must be examined in the customs area by inspection units to determine whether handling was performed in accordance with applicable technical legislation, and the application must not be finalized until handling is complete. If necessary corrections are found to have been made, the application is finalized as "Acceptance: Inspection Result." Handling operations obtained from the customs authority without applying to the relevant inspection unit are not accepted.

4.4.1 Requests for Handling of the CE Marking

For products bearing CE marking, requests for handling the CE marking may be considered where the conditions listed in Article 5(1), entitled "Obligations of the Manufacturer," of the CE Marking Regulation are met, no manifest non-compliance is identified, and the company submits a trademark registration certificate and a technical file for products for which it can demonstrate that it is the manufacturer.

4.4.2 Requests for Handling of Adapters

Handling of adapters of products found non-compliant because of adapters supplied with the product is permitted provided that:

- It is documented that non-compliant adapters to be separated from the application products have been surrendered to the customs authority where they are located for return to origin, transit directly or via a free zone to a third country, sale for export, or disposal by destruction at the owner's expense, pursuant to Article 181(4)(ç) of the Customs Regulation; and
- Products are tested with compliant adapters and receive a positive result.

4.5 Objections to Inspection Outcomes

An application may be reopened for inspection where it was rejected because documents could not be submitted on time, or where the company objects on the ground that the inspector finalized the inspection as rejected despite a marking, brand, model, etc. being present but possibly overlooked, or submits an out-of-scope request. Companies may object to the inspection outcome through the objection button in TAREKS once only, within one year, for rejected applications. The objection period for test results is 15 business days.

For reopened applications, no additional 45-day period is granted; the importer must promptly submit the missing document, objection petition, technical file if requested, and other obligations. Companies may never object to applications finalized as "Rejection: Document Not Issued by Its Purported Issuer" or "Rejection: Misleading Transaction." However, for applications finalized as "Rejection: Missing Document," missing documents; for "Rejection: Missing Marking," documents such as pictures, designs and schematics showing where the missing marking will be placed; for applications closed as "Rejection: Test Result," the petition requesting retesting; and in all cases additional documentation requested by the inspector, must be uploaded within no more than 15 business days. Applications of companies failing to meet these obligations in this period are again finalized with the same rejection and no further objection through the system is permitted.

Where an application is again rejected despite an objection through the system within one year, the Directorate General may assess, once only, a request to reopen the application to enable the company to remedy deficiencies. No additional 45-day period is granted for reopened applications; the importer must submit the missing document within 15 business days.

4.6 Transit Requests for Non-Compliant Products

If companies wish to transit products covered by an application finalized as "Rejection," a favorable opinion of the Directorate General must be obtained pursuant to Article 181(4)(ç) of the Customs Regulation. Such companies must apply in writing to the Directorate General; state the country to which the product will be transited; declare that the product complies with that country's legislation; and complete fully the documents in Annex 9, in accordance with the "Transit Permission" heading in the "Old Help" tab of TAREKS. A favorable opinion of the Directorate General is not required where products are returned to origin.

The utmost care must be exercised against the possibility that all non-compliant products intended for transit trade, or part of the consignment after it is divided, may be attempted to be placed on the Turkish market in the name of the relevant and/or different companies and thereby become subject to inspection. Suspicious applications must promptly be reported to the Directorate General.

If avoidance of inspection through unlawful means, such as unauthorized transit trade, is identified, the absence of products from customs and those avoidance acts are taken into account and the application is finalized as "Rejection: Misleading Transaction."

5. PRODUCT-SPECIFIC PRINCIPLES

5.1 Required Documents and Core Product Markings by Product Class

Devices within the scope of the Medical Devices Regulation

Product class	Marking	Documents
Class I (not sterile, reusable or with measuring function)	CE	EU Declaration of Conformity (Annex IV); Annex IX, Parts I and III.
Class I (sterile, reusable and/or with measuring function)	CE and Notified Body number	EU Declaration of Conformity (Annex IV); Quality Management System Certificate (Annex XI, Part A); Production Quality Assurance System (Annex IX, Parts I and III and, for each device category, Annex IX, Part II).
Class IIa	CE and Notified Body number	EU Declaration of Conformity (Annex IV); EU Quality Management System Certificate (one part of Annex XI, Article 10 or 18); EU Quality Assurance Certificate plus technical documentation specified in Annexes II and III; Annex IX Parts I and III and Annex IX Part II for each generic device group.
Class IIb	CE and Notified Body number	EU Declaration of Conformity (Annex IV); EU Quality Management System Certificate (Annex XI); EU Product Conformity Verification Certificate (Annex XI) and EU Type Examination Certificate (Annex X); Annex IX, Part II.

Class III	CE and Notified Body number	EU Declaration of Conformity (Annex IV); Quality Management System Certificate (Annex IX, Parts I and III); Technical Documentation Assessment; Production Quality Assurance Certificate (Annex XI, Parts A and B); EU Type Examination Certificate (Annex X); Product Verification Certificate.

Note (Class IIb): A Technical Documentation Certificate is requested for implantable products. This certificate is not requested for products within WET (Well-Established Technologies).

Devices within the scope of the In Vitro Diagnostic Medical Devices Regulation (IVDR)

Product class	Marking	Documents
Class D	CE and Notified Body number	EU Declaration of Conformity; EU Quality Management System Certificate (Annex IX, Parts I and II); EU Technical Documentation Assessment (Annex IX, Part III); EU Production Quality Assurance Certificate (Annex XI); EU Type Examination Certificate (Annex X).
Class C	CE and Notified Body number	EU Declaration of Conformity; EU Quality Management System Certificate (Annex IX, Parts I and II); EU Technical Documentation Assessment Certificate for at least one representative device for each generic device group; EU

		Production Quality Assurance Certificate (Annex XI); EU Type Examination Certificate (Annex X).
Class B	CE and Notified Body number	EU Declaration of Conformity; EU Quality Management System Certificate (Annex IX, Parts I and II); EU Technical Documentation Assessment Certificate for at least one representative device for each device category.
Class A (sterile)	CE and Notified Body number	EU Declaration of Conformity; EU Quality Management System Certificate (Annex IX—sterilization); EU Production Quality Assurance Certificate (Annex XI—sterilization).
Class A (non-sterile)	CE	EU Declaration of Conformity.

For personal testing devices, near-patient testing devices and companion diagnostic devices, an EU Technical Documentation Assessment Certificate is also required in addition to the above certificate.

5.2 Information on Transitional Arrangements for UDI

Definitions: UDI is a series of numeric characters enabling the unambiguous identification of specific devices on the market. UDI-DI is a unique numeric or alphanumeric code specific to a device model and is also used as an access key to information stored in the UDI database. Basic UDI-DI is the primary identifier of a device model, assigned at the usage-unit level; it is the primary key for records in the UDI database and is referred to in relevant certificates and EU declarations of conformity. Master UDI-DI is the unique identifier used to group certain highly individualized medical devices that share specified clinically relevant parameters; for example, contact lenses with the same combination of design parameters such as base curvature and diameter must be assigned one Master UDI-DI. UDI-PI states in

EUDAMED's UDI/Device Registration module whether a serial number, batch number or another number is used.

Identifier	Other medical devices	Contact lenses	On label	EUDAMED
Basic UDI-DI	Yes	Yes	No	Yes
Master UDI-DI	–	Yes	Yes	Yes
UDI-DI	Yes	–	Yes	Yes
UDI-PI	Yes	Yes	Yes	No

Note: UDI-PI information containing serial number, lot number or expiry-date information must appear on the label and/or sales packaging. These details may appear separately or all in a QR code. UDI-DI refers to the barcode number, whereas UDI-PI is the code identifying the production unit. The barcode on the label and the barcode registered in the Product Tracking System (ÜTS) must be identical. UDI consists of UDI-DI and UDI-PI components.

For completed medical devices, inspections must be conducted, regardless of their production dates, on the basis of the date they are placed on the market or put into service after completion of the transition period. Under legislation currently in force, UDIs containing UDI-DI and UDI-PI must be affixed by the manufacturer to the medical device and, where applicable, to all higher levels of packaging; inspections must be completed accordingly.

MDR transition requirement	Implantable devices and Class III	Class IIa and IIb	Class I
UDI carrier on device labels (MDR Art. 123(3)(f), Art. 27(4))	26 May 2021	26 May 2023	26 May 2025
Direct marking of reusable devices (MDR Art. 123(3)(g), Art. 27(4))	26 May 2023	26 May 2025	26 May 2027

For contact lenses, under Commission Delegated Regulation (EU) 2023/2197 of 10 July 2023, as amended, Master UDI-DI becomes mandatory for contact-lens manufacturers as of 9 November 2026. Master UDI-DI is not mandatory on labels of contact lenses manufactured before 9 November 2026.

IVDR transition requirement	Class D IVDs	Class C and B IVDs	Class A IVDs
UDI carrier on device labels (IVDR Art. 113(3)(e), Art. 24(4))	26 May 2023	26 May 2025	26 May 2027

If an EU Declaration of Conformity containing Basic UDI-DI information cannot be submitted in medical-device inspections, the application is finalized as "Rejection: Inspection Result." If UDI is absent from the product and packaging even though applicable, the application is finalized as "Rejection: Missing Marking."

5.3 Products Listed in Annex XVI to the Medical Devices Regulation

In the import-inspection process for non-medical-purpose products listed in Annex XVI to the Medical Devices Regulation, products must also comply with the Communiqué on Determining Common Specifications for Groups of Products without a Medical Purpose Listed in Annex XVI to the Medical Devices Regulation. Under the transitional provisions of that Communiqué, the date of placing on the market is important; to resolve uncertainty, documents drawn up under legislation with which the product had to comply before becoming subject to that Regulation may be examined. Applications able to benefit from the transitional provisions of the said Communiqué (before 22 June 2023) must be finalized as "Conditional Acceptance: Inspection Result."

Situation	Transition provisions
Products first placed on the market after 22 June 2023	Products must comply with the Medical Devices Regulation published in Official Gazette No. 31499 (duplicate issue) dated 2 June 2021.
Annex XVI products first placed on the market before 22 June 2023, where clinical investigation will be conducted	May be placed on the market without conditions until 22 June 2024; until 22 December 2024 provided an application for clinical investigation is made to the competent authority; until 31 December 2027 provided the clinical investigation has started; until 31

		December 2029 provided a written agreement has been made with a Notified Body. After 31 December 2029, certification under Regulation (EU) 2017/745 by a Notified Body is required.	
Annex XVI products first placed on the market before 22 June 2023, where no clinical investigation will be conducted		May be placed on the market without conditions before 1 January 2027; until 31 December 2028 provided a written agreement has been made with a Notified Body. After 31 December 2028, certification under Regulation (EU) 2017/745 by a Notified Body is required.	
Operating principle	Product	Description	Assessment under EU legislation
Heating/Cooling	Skin-cooling system for lipolysis	Used in non-invasive body contouring treatment to reduce fat-cell volume by cooling.	Falls under Annex XVI, product group 1; Class IIa (Rule 10).
Heating/Cooling	Hot/cold facial massage device	Used for facial skin care; soothes skin and accelerates circulation.	No medical purpose or special technology; therefore concluded not to be a medical device.
Ultrasound (sound waves)	Focused ultrasound system for lipolysis	Uses high-intensity focused ultrasound energy to non-invasively disrupt subcutaneous fat tissue.	Falls under Annex XVI, product group 1; Class IIb.
Ultrasound (sound waves)	Ultrasonic facial massage device	Applies high-intensity waves to the user's skin.	Cosmetic if it affects only the epidermis. Generally, a sonic facial massager with no medical claim affects only the epidermis

			and is not considered a medical device.
Optical (light)	Laser-operated surgical instrument	Removes unwanted brown spots, sun freckles or tattoos on skin.	Falls under Annex XVI, product group 1; Class IIb.
Optical (light)	Light-based hair-removal device	Uses light or intense pulsed light to slow hair growth by damaging hair follicles.	IPL hair-removal devices fall under Annex XVI, product group 1.
Electrical	Radiofrequency energy system	Delivers radiofrequency energy into deep skin tissues; used for skin tightening and wrinkle reduction.	Falls under Annex XVI, product group 1; Class IIb.
Electrical	Electric facial massage device	Uses microcurrent to improve skin-care results and metabolism.	Cosmetic if it affects only the epidermis. Generally, an electric facial massager with no medical claim affects only the epidermis and is not considered a medical device.

Source: Journal of Medical and Biological Engineering, volume 40, pp. 101–111 (2020).
Note: See MDCG 2023-5 for full guidance.

5.4 Storage/Preservation/Use Conditions

Information category	Scope (example)	Shown on label	Instructions for use & system
Specific storage conditions	e.g., -3 / +12 °C	MANDATORY	MANDATORY

General storage conditions	e.g., -30 / +70 °C	Optional	MANDATORY
Use conditions	Device operating environment, etc.	Optional	MANDATORY

6. ANNEXES

Annex 1. Physical Inspection and Sampling Report

IMPORT INSPECTIONS
PHYSICAL INSPECTION/SAMPLING REPORT

Date: …/…/….
Application Date/No.:
Name/Tax No. of Importer:
Location of Products:
Items Identified in Physical Inspection (manufacturer/importer information, brand-model, marking, presence of warnings, product type, etc.)
Example 1: CE marking, brand-model and manufacturer information are present and compliant. Importer information is missing.
Example 2: CE marking is present but its design is non-compliant.
If a sample was taken:
Total number of samples taken:
Number of witness samples taken:

I accept the accuracy of the information stated above. I accept that the specimen(s)/sample(s) taken/examined under this report represent all relevant products within the application stated above and that their results are binding. I undertake that all costs arising from testing will be borne by us and accept that inspections will be finalized according to the test result. After notification of the inspection outcome, I accept that we may object to the test result only within 15 business days and undertake that, if we do not collect the sample at the end of the objection period, we will make no claim regarding those samples.

Company Representative
Full Name:
Signature:
Date:

Trade Inspector/Assistant Trade Inspector
Full Name:
Signature:
Date:

Annex 2. EU Declaration of Conformity Specimen

EU DECLARATION OF CONFORMITY

The EU Declaration of Conformity contains all of the following information:

1. Name, registered trade name or registered trademark of the manufacturer and, where applicable, authorized representative; where already issued, the Single Registration Number referred to in Article 31; and the address of their registered place of business at which they can be contacted.

2. A statement that the EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

3. Basic UDI-DI as referred to in Annex VI, Part C.

4. Product and trade name, product code, catalogue number or other unambiguous references, such as a photograph where applicable, together with intended purpose, enabling identification and traceability of the device covered by the declaration. Except for product or trade name, information enabling identification and traceability may be provided through the Basic UDI-DI referred to in item 3.

5. Risk class of the device under the rules in Annex VIII.

6. A statement that the device covered by this declaration complies with this Regulation and, where applicable, other relevant EU legislation requiring an EU Declaration of Conformity.

7. References to common specifications used and for which conformity is declared.

8. Where applicable, name and identification number of the Notified Body, a description of the conformity-assessment procedure performed, and identification of certificate(s) issued.

9. Where applicable, additional information.

10. Place and date of issue of the declaration; name and function of the signatory; indication of on whose behalf the person signs; and signature.

Annex 3. Minimum Content of Certificates Issued by Notified Bodies

1. Name, address and identification number of the Notified Body.

2. Name and address of the manufacturer and, where applicable, authorized representative.

3. Unique number identifying the certificate.

4. Single Registration Number of the manufacturer (MDR Article 31/IVDR Article 29).

5. Date of issue.

6. Validity (expiry) date.

7. Where applicable, data necessary to clearly identify the device(s).

8. Where applicable, reference to each previous certificate.

9. Reference to the Regulation and relevant Annex under which conformity assessment was conducted.

10. Examinations and tests carried out, for example references to relevant common specifications, harmonized standards, test reports and audit report(s).

11. Where applicable, reference to relevant parts of technical documentation or other certificates necessary for placing the covered device(s) on the market.

12. Where applicable, information on surveillance performed by the Notified Body.

13. Conclusions of the Notified Body's conformity assessment for the relevant Annex.

14. Conditions or limitations concerning certificate validity.

15. Legally valid signature of the Notified Body under relevant legislation.

Annex 4. UDI Label Specimen and Explanations

UDI label specimen; Master UDI-DI label specimen.

Annex 5. Examples of Non-Compliant CE Marking

- Use of a typeface other than the one prescribed by the Regulation.
- A distinct gap between the letters C and E.
- A serious size difference between the letters C and E.

Annex 6. Medical Device Symbols Used for Active and Non-Active Devices

Medical-device symbols must be used together with medical-device labels when supplied. These symbols form part of the regulatory requirements of leading regulators, including the EU and FDA.

Applicable labelling standards: EN ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements; EN ISO 20417:2021 Medical devices — Information to be supplied by the manufacturer; EN 15986:2011 Symbol for use in the labelling of medical devices — Requirements for labelling of medical devices containing phthalates; EN ISO 3826-2:2008 Plastics collapsible containers for human blood and blood components — Part 2: Graphical symbols for use on labels and instruction leaflets.

Symbol description
Manufacturer (name and address)
Authorized representative in the European Community/European Union
Date of manufacture
Use-by date
Batch code
Catalogue number
Serial number
Importer
Distributor
Model number
Country of manufacture
Sterile
Sterilized using aseptic processing techniques
Sterilized using ethylene oxide
Sterilized using irradiation
Sterilized using steam or dry heat
Do not resterilize
Non-sterile
Do not use if package is damaged and consult instructions for use
Sterile fluid path
Sterilized using vaporized hydrogen peroxide
Single sterile barrier system
Double sterile barrier system
Single sterile barrier system with protective packaging inside
Single sterile barrier system with protective packaging outside
Fragile, handle with care
Keep away from sunlight
Protect from heat and radioactive sources
Keep dry
Temperature limit

Humidity limitation
Atmospheric pressure limitation
Biological risks
Do not re-use
Consult instructions for use or consult electronic instructions for use
Caution
Contains or presence of natural rubber latex
Contains human blood or plasma derivatives
Contains a medicinal substance
Contains biological material of animal origin
Contains biological material of human origin
Contains hazardous substances
Contains nano materials
Single patient multiple use
In vitro diagnostic medical device
Control
Negative control
Positive control
Contains sufficient for <n> tests
For IVD performance evaluation only
Sampling site
Fluid path
Non-pyrogenic
Drops per milliliter
Liquid filter with pore size
One-way valve
Patient number
Patient name
Patient identification
Patient information website
Health care centre or doctor
Date
Medical device
Translation
Repackaging
Unique device identifier

Annex 7. Further Processing Undertaking

TO THE MINISTRY OF TRADE

Pursuant to the Communiqué on Medical Device Import Inspection (Product Safety and Inspection: 202…/16), we accept and undertake that we will bring the … brand, … model products that we wish to import into final form in compliance with applicable technical legislation within no later than 6 months; that we will not transfer them to third parties in any manner during that period; and that we will not offer them for sale on the domestic market before they are brought into final form. If we act otherwise, we accept and undertake that, pursuant to Article 13(1)(d) of the Decision on the Technical Regulations Regime enacted by Presidential Decision No. 6038 dated 14 September 2022, we will pay to the budget, as revenue, the Turkish lira equivalent calculated using the foreign-exchange selling rate of the Central Bank of the Republic of Türkiye on the date the relevant tax office notifies us, of 60% of the CIF value of the imported product, and that payment will be made in accordance with the Law No. 6183 dated 21 July 1953 on the Procedure for the Collection of Public Receivables. We also accept the obligations and sanctions in Law No. 7223 dated 5 March 2020 if the relevant competent authority determines that products from the imported consignment brought into final form within the stated period do not comply with the provisions of the said Regulation.

Importer’s Trade Name
Authorized Signature
Date
Address:
Name of tax office:
Tax registration number:
Date and number of customs declaration:
CIF value of imported product:
Photographs of the imported product and its final form:

Annex 8. Specimen Rejection Inspector Message

As a result of the reviews conducted, the application has been finalized as “Rejection: …” on the basis of … reasons. You have the right to return the products to origin, transit them directly or via a free zone to a third country, sell them for export, or surrender them to the customs authority where they are located for disposal by destruction at the owner’s expense. If you object through the objection button in the system and promptly submit an objection petition to the relevant Group Presidency, your objection to the inspection outcome may be assessed. The objection period for test results is 15 business days.

Annex 9. Transit Authorization Documents

Where inspections performed under Product Safety and Inspection (PSI) Communiqués establish that products do not comply with their technical regulation and/or are unsafe, the application submitted by the importer to the Ministry for transit of the products to a third country must include the following matters and meet the following conditions:

1. Transit may not be made to countries that are members of the European Union Common Market, members of the European Free Trade Association (EFTA), the Turkish Republic of Northern Cyprus, or free zones.

2. Opinions may be sought from relevant institutions, organizations and Directorates General concerning countries of transit in light of developments in international trade.

3. For the importer's application to the Ministry: (a) the table in Annex 9C completed appropriately; (b) declaration and undertaking that the product complies with the legislation of the transit country (Annex 9A); (c) warehouse declaration, bill of lading, invoice copy and other documents; and (d) signature circular and/or power-of-attorney copy demonstrating that the applicant is authorized to sign and/or represent, must be included.

4. If the importer transfers products to another company, the transferee's application to the Ministry must include: (a) the table in Annex 9D completed appropriately; (b) documents such as the invoice evidencing transfer; (c) declaration and undertaking of compliance with the transit country's legislation (Annex 9B); (d) warehouse declaration, bill of lading, invoice copy and other documents; and (e) signature circular and/or power-of-attorney copy demonstrating signing/representation authority.

5. For the transferee to obtain transit permission, it must be registered in TAREKS.

6. The transit-permission request submitted to the Ministry is approved once it is confirmed that the stated conditions are met. The relevant customs authority and company are notified that transit permission has been granted.

7. To prevent attempts to place transited products on the Turkish market again, the General Directorate of Customs and the Directorate General of Trade Research and Risk Assessment are notified so that the products can be followed for at least 3 months.

8. Information about the transit procedure is entered into TAREKS to prevent later re-importation of transited products into Türkiye through the system.

Annex 9A

TO THE MINISTRY OF TRADE
(Directorate General for Product Safety and Inspection)

Following the inspection conducted under Product Safety Inspection Communiqué No. …, application No. …, submitted through the Risk-Based Control System in Foreign Trade by company … for products with customs tariff code … and description …, was finalized with rejection. Under Article 181(4)(ç) of the Customs Regulation, we wish to transit the products rejected as a result of inspection to … (country name). We declare and undertake that the said products comply with the legislation of … (country name), the country of transit.

We respectfully submit this for your action and consideration.

Importer or Representative
Name/Trade Name
Company Stamp
Authorized Signature(s)
Date

Annex 9B

TO THE MINISTRY OF TRADE
(Directorate General for Product Safety and Inspection)

Following the inspection conducted under Product Safety Inspection Communiqué No. …, application No. …, submitted through the Risk-Based Control System in Foreign Trade by company … for products with customs tariff code … and description …, was finalized with rejection. The said products were transferred and delivered by that company to company … under transfer invoice No. …. Under Article 181(4)(ç) of the Customs Regulation, we wish to transit the products rejected as a result of inspection to … (country name). We declare and undertake that the said products comply with the legislation of … (country name), the country of transit.

We respectfully submit this for your action and consideration.

Transferee Company or Representative
Name/Trade Name
Company Stamp
Authorized Signature(s)
Date

Annex 9C. Products Subject to Transit Request

Importer tax number	TAREKS application	Bill of lading date	Bill of lading number	Customs tariff code/Product type	Quantity

Importer or Representative
Name/Trade Name
Company Stamp
Authorized Signature(s)
Date

Annex 9D. Products Subject to Transit Request

Transferor tax number	Transferee tax number	TAREKS application	Bill of lading date	Bill of lading number	Customs tariff code/Product type	Quantity

Transferee Company or Representative
Name/Trade Name
Company Stamp
Authorized Signature(s)
Date